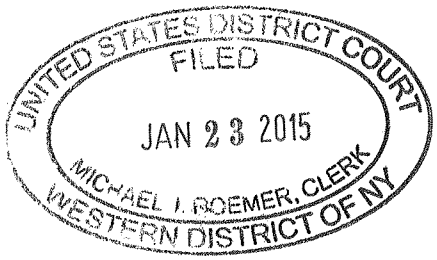

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel.,
JASON W. NICKELL,

Plaintiffs,

-v-

MEDTRONIC, INC., ST. JUDE MEDICAL, INC. AND BOSTON SCIENTIFIC CORPORATION,

Defendants.

09-CV-0203(S)

UNITED STATES' NOTICE OF INTERVENTION IN PART FOR PURPOSES OF SETTLEMENTAND DECLINATION IN PART

The United States, Relator, and Defendant Medtronic, Inc., ("Medtronic") have reached a settlement agreement to resolve this action. In light of this agreement, and for the purpose of effectuating and formalizing that resolution, pursuant to the False Claims Act, 31 U.S.C. §§ 3730(b)(2) and (4), the United States respectfully advises the Court of its decision to intervene in part and decline in part for the purposes of settlement.

Specifically, the United States intervenes in this action with respect to civil claims predicated upon the following factual allegations (the "Covered Conduct):

During the time period January 1, 2007 through December 31, 2011, Medtronic knowingly caused false or fraudulent claims for the implantation of SCS devices to be submitted to Medicare and TRICARE by the certain physicians identified in Attachment A to the Settlement Agreement.

More specifically, throughout 2007 to 2011, Medtronic, through its sales representatives, promoted the use of Medtronic SCS devices for use outside the spinal column area in a procedure variously described as "subcutaneous stimulation" or "SubQ Stimulation." In the "SubQ" procedure, the leads, which are FDA-approved for use alongside the spinal column, are placed by the physician in the subcutaneous tissue just beneath the skin in an area of pain, most often in the lower back. Once implanted in the subcutaneous tissue, the leads provide electrical impulses that create a "tingling" sensation for the patient intended to alleviate chronic pain. Medtronic's alleged conduct caused the identified physicians to submit claims for payment to Medicare and TRICARE for non-covered services.

These were non covered services because the company's SCS devices were not approved or cleared by FDA for use in "SubQ" procedures; the use of the SCS devices in SubQ procedures was considered investigational by CMS; efficacy had not been established with sufficient clinical evidence; and FDA required a clinical study under an investigational device exemption to establish the safety and efficacy of the SCS devices when used in the SubQ procedure, as well as approved labeling addressing lead placement, patient selection, and device programming, none of which occurred during the time period in question.

Medtronic sales representatives arranged to have physician-customers attend company-sponsored didactic instructional programs known as "on-site training programs," at which some physician customers received instructional training on how to use Medtronic SCS devices in SubQ procedures.

In discussions with healthcare providers, Medtronic personnel incorrectly identified CPT Code 64555 as an appropriate billing code for "SubQ" even though an outside coding expert engaged by Medtronic had warned "Medtronic reps should not be going around saying that [CPT Code] 64555 is correct for subq leads." Following this comment, Medtronic representatives continued to identify CPT Code 64555 as an appropriate code for submitting claims for "SubQ" procedures.

As a result of the foregoing conduct, the United States alleges that Defendants knowingly caused false or fraudulent claims to be submitted to Medicare by the physicians identified in Attachment A to the Settlement Agreement.

The United States declines intervention with respect to all other claims and all other defendants alleged in this action.

Under the terms and conditions of the settlement agreement among the parties, the United States and Relator will file a Notice of Dismissal following the settlement payment from Medtronic.

Finally, the United States hereby requests that the Court unseal the Relator's Complaint, this Notice of Intervention, and all subsequent filings following this Notice of Intervention. The United States respectfully requests that all other filings in this matter remain under seal and not be made public (including, but not limited to, any applications filed by the United States for extensions of the sixty-day investigative period, any applications

for partial lifting of the seal, and any orders previously entered in this matter). A Proposed Order is filed herewith.

Respectfully submitted,

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Acting Assistant Attorney General

JAMES P. KENNEDY
Attorney for the United States
Acting Under Authority Conferred
by *28 U.S.C. § 515*

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DATED: January 16, 2015
AT: Buffalo, New York

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel.,
JASON W. NICKELL,

Plaintiffs, 09-CV-0203(S)

-v-

MEDTRONIC, INC., ST. JUDE MEDICAL, INC. AND BOSTON SCIENTIFIC CORPORATION,

Defendants.

CERTIFICATE OF SERVICE

This is to certify that copies of the foregoing Notice of Intervention in Part for Purposes of Settlement and Declination in Part (filed *in camera* and under seal) have been served by Certified Mail, Return Receipt Requested, this 16th day of January 2015, on:

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